Summary of Safety and Effectiveness
(as required by 21 CFR 807.92)

AUG - 8 2008

K081457

ATRILAZE™ Surgical Ablation System
[(K08XXXX)]

Submitter:
MedicalCV, Inc.
9725 South Robert Trail
Inver Grove Heights, MN 55077
USA

Contact:
Kirk S, Honour
Regulatory, Clinical & Quality Management
Phone: 651-452-3000
Fax: 651-452-4948

Date of Summary:	[DATE]
Product Code:	GEX, OCL
Classification Name:	Laser Instrument, Surgical Powered
Common Name:	Surgical Laser Instrument
Proprietary Name	ATRILAZE™ Surgical Ablation System

Description of Device:

The ATRILAZE™ Surgical Ablation System consists of a Laser Energy Generator, system cart, fluid delivery pump, fluid delivery tubing set and a fixed or flexible surgical ablation wand of various lengths. The wand is an intraoperative, sterile, single-use device designed to apply laser energy to cardiac tissue. The fluid delivery tubing set is a single-use device having a sterile fluid path designed for the delivery of sterile saline solution to the wand tip. The fluid delivery tubing may be provided together with the wand or as an accessory device. The fluid delivery pump and laser energy generator are sold separately. The wand includes a ridged metallic shaft or a flexible shaft of various lengths, and is equipped with a 905 SMA connector cable which attaches to the laser energy generator output connector. The emitted laser energy is directed toward the target tissue from the end of the optical fiber which rides within the flexible track.

Statement of Intended Use:

The ATRILAZE™ Surgical Ablation System is indicated for delivery of 810nm, 1064nm or 1083nm laser light to soft tissue to include cardiac tissue during surgical procedures. Indications include the incision, excision, dissection, vaporization, ablation, or coagulation of soft tissue.

The ATRILAZE™ Surgical Ablation System Accessories are intended for use in the support of the delivery of laser light to soft tissue to include cardiac tissue during surgical procedures.

Warning:

The ATRILAZE™ Surgical Ablation System is not indicated for the treatment of cardiac arrhythmias.

The risk of actual damage to adjacent organs from the instrument exists and perforation, rupture or tearing of tissue, may occur as a complication of laser use. Burns can occur if the laser energy is not correctly applied. These complications may be serious.

Technological Comparison:

The ATRILAZE™ Surgical Ablation System was compared to the current ATRILAZE™ Surgical Ablation System (K060680).

Both the currently available device and the ATRILAZE™ wand as reviewed in this 510(k) are provided sterile with a sterile fluid path for saline delivery at the laser tip. Both fiber optic delivery systems utilize the same laser energy generator and are connected via an SMA 905 connector to deliver laser energy to the target tissue.

For purposes of this submission, the ATRILAZE™ Surgical Ablation System was compared to the following predicate devices: ATRILAZE™ Surgical Ablation System (K060680).

Testing:

Testing demonstrated that adherence to specifications was demonstrated and the lesions obtained using the ATRILAZE™ wand with 1083nm laser light are substantially equivalent to those obtained with the currently cleared ATRILAZE™ Surgical Ablation System wavelengths.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MedicalCV, Inc.
% Mr. Kirk S. Honour
Regulatory, Clinical & Quality Management
9725 South Robert Trail
Inver Grove Heights, Minnesota 55077-4424

AUG - 8 2008

Re: K081457
Trade/Device Name: ATRILAZE™ Surgical Ablation System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical insgrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 21, 2008
Received: May 28, 2008

Dear Mr. Honour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(K) Number: K081457

Device Name: ATRILAZE™ Surgical Ablation System

Indications for Use:

The ATRILAZE™ Surgical Ablation System is indicated for delivery of 810nm, 1064nm or 1083nm laser light to soft tissue to include cardiac tissue during surgical procedures. Indications include the incision, excision, dissection, vaporization, ablation, or coagulation of soft tissue.

The ATRILAZE™ Surgical Ablation System Accessories are intended for use in the support of the delivery of laser light to soft tissue to include cardiac tissue during surgical procedures.

Warning:

The ATRILAZE™ Surgical Ablation System is not indicated for the treatment of cardiac arrhythmias.

The risk of actual damage to adjacent organs from the instrument exists and perforation, rupture or tearing of tissue, may occur as a complication of laser use. Burns can occur if the laser energy is not correctly applied. These complications may be serious.

Prescription Use__X__ OR Over–the-Counter Use____
(Per 21 CFR 801.109)

(Please do not write below this line – Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081457